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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/684,066	10/06/2000	Rama Ranganathan	UTSD:645US/MTG	2858
7590	10/20/2004			
Mark T. Garrett FULBRIGHT & JAWORSKI L.L.P. SUITE 2400 600 CONGRESS AVENUE AUSTIN, TX 78701				
EXAMINER CLOW, LORI A				
ART UNIT		PAPER NUMBER		
1631				
DATE MAILED: 10/20/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	09/684,066	RANGANATHAN ET AL.	
	Examiner	Art Unit	
	Lori A. Clow, Ph.D.	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2004.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Applicants' arguments, filed 15 July 2004, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-18 are currently pending.

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-18 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, as stated in the Previous Office Action. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

#### **Response to Applicant's Arguments**

Applicant argues that the claims are enabled and makes several arguments that will be addressed below in the order in which they were presented.

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*Claim 1, argument a. "accessing data"*

Applicant again asserts that the Office believes that Applicant is claiming the creation of a multiple sequence alignment (MSA) based upon the statement in the Office Action dated March 2004 "what polymers are selected, on what basis are they selected, and how are they aligned in a MSA?"

Again, it is acknowledged that MSA techniques are **well known** in the art and that Applicant is **not** claiming a method to perform an MSA. Applicant is claiming the identification of positions in a polymer family. Again, Applicant has ignored the questions pertaining to the accession of data in terms of **what polymers** are utilized. The question of enablement, as was pointed out to Applicant in the Interview of 18 December 2003, is whether the specification teaches how to perform this method with any polymer. For instance, identifying one or more evolutionarily conserved amino acid positions in a chemical polymer is nonsense if the chemical polymer does not include protein. Applicant clearly states in the response that this method is applicable to **any** polymer, including drugs, chemical polymers etc. Yet, Applicant does not provide any specifics as to how this is performed with any of the argued polymers other than polypeptides and the specification is devoid of any information showing an alignment of chemical or other polymers and how these types of polymers would be used in said invention. The specification only points to a limited example using the PDZ **protein** family. The specification, at page 6, indicates that proteins are polymers that can be used, but is **silent as to other polymers** amenable to the method. For instance, are polyacrylamide polymers able to be used in this method? How would such non-protein polymers be aligned? Could free energy calculations be performed? The specification, at page 16, indicates that only protein sequences

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can be aligned, but is completely devoid of information as to how any other type of polymer is to be selected and aligned. Further, the claims do not set forth that the polymers to be aligned are from a single protein family or from related proteins. There is no requirement for a base level of similarity for the multiple sequence alignment such that one of ordinary skill in the art would be able to select appropriate sequences for use in this method. The specification, at page 17, indicates that “protein families” are used, but does not speak to how such families are correctly aligned.

*Claim 1, argument b. “identifying one or more evolutionarily conserved positions”*

Applicant states that “in judging enablement, this step must be read in conjunction with the specification which explains that “evolutionarily conserved amino acid positions” refers to particular positions within a multiple sequence alignment which display a non-zero  $\Delta G^{\text{stat}}$  as calculated by Equation 4” and states that the “specification also provides source code”. This is not persuasive in that the claims do not contain limitations of source code. Applicant is reminded that limitations from the specification cannot be read into the claims.

Applicant goes on to state that “the assertion (that the specification only points to a limited example using the PDZ protein family) is legally insufficient. It does not carry the Office’s burden of providing evidence or reasoning why the claimed equation cannot be applied to MSAs of polymer sequences other than the PDZ protein family”. The point of the enablement rejection is not that the equation should be limited to PDZ protein sequences. Rather, the claim reads on **any** polymer sequence and the specification is not enabling for any polymer for the reasons previously set forth. It is noted that working examples are not required for enablement, but are helpful when the specification is otherwise deficient. In the instant case, the specification

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provides an example of the implementation of the equation for PDZ protein sequences, but no other polymer sequences. For these reasons, the rejection is maintained.

### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites "a program storage device readable by the machine of claim 2 and encoding instructions executable by the machine for performing the operations recited in the claim". Claim 2 is not directed to a machine. It is directed to a method. Furthermore, it is unclear what "claim" is intended. Clarification is requested.

No claims are allowed.

### **Inquiries**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center Number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

October 18, 2004  
Lori A. Clow, Ph.D.  
Art Unit 1631  
*Lori A. Clow*

MARJORIE MORAN  
PATENT EXAMINER

*Marjorie A. Moran*  
10/18/04